

**510(k) Summary**  
(as required by 21 CFR 807.92)

16081630

JUL 29 2008

510(k) Number:	
Submitter:	Image Diagnost International GmbH
Address:	Balanstraße 57 81541 München Germany
Contact:	Dr. Peter Heinlein
Telephone:	++49 (89) 450 3666
Date:	April 2007
Device Name: Trade Name:	MammoWorkstation
Common Name:	Medical imaging software
Classification Name:	Picture archiving and communication system
Classification:	Class II CFR 892.2050 System, Image Processing, Radiological, LLZ
Predicate Devices:	<p>1. Cedara Software Corp. 510(k) Number: K040468 Device: Cedara I-ReadMammo</p> <p>2. Sectra Imtec AB 510(k) Number: K063093 Device: Sectra Workstation IDS5/mx.net</p> <p>3. GE Healthcare Integrated IT Solutions 510(k) Number: K063628 Device: Centricity Radiology RA600</p>

**Device Description:**

The MammoWorkstation is a medical image review workstation software for diagnostic and screening mammography. It is a software product. The product consists of features that allow the qualified medical professional to review patient medical images and to apply tools to cover the relevant aspects of an efficient review workflow. In addition, the system supports creation of report documents.

**Indications for use:**

"MammoWorkstation is designed to assist radiologists in conducting primary diagnostic review for diagnostic and screening mammography through flexible and interactive manipulation of multi-modality softcopy images.

It provides image review, manipulation, analysis, post-processing and printing capabilities that support image management display needs in the medical environment.

MammoWorkstation is designed to give easy and economic access to and display of multi-modality softcopy images, structured reports, and CAD results through interfaces to various image storage devices using DICOM or similar interface standards. It supports creation of structured reports according to the DICOM breast imaging report templates.

MammoWorkstation supports teleradiology and teleconferencing providing access to multi-modality softcopy images and structured reports in multiple locations within and outside the hospital.

Lossy compressed mammographic images must not be used for primary diagnostic interpretation unless approved for use in digital mammography.

Display monitors used for primary diagnostic interpretation of mammographic images must be approved for use in digital mammography."

All images sent to or imported in the MammoWorkstation must conform to regulatory requirements. Image quality must conform with applicable quality guidelines. All modalities must be certified for soft-copy reading.

(Source: Users Manual, MammoWorkstation Version 3.3.2, section 2.3.1)

#### Techological Characteristics:

The MammoWorkstation Software will run on Windows 2000 and Windows XP operating system for PCs. Appropriate approved displays for softcopy reading of digital mammography are required for diagnostic reading.

#### Performance Data:

The subject is developed in an environment according to ISO 13485:2003, IEC 62304, and ISO 14971. Further it complies with ACR/NEMA Digital Imaging Communications in Medicine version 3.0.

#### Comparison to predicate device:

The intended use and technological characteristics of MammoWorkstation are substantially equivalent to those of the predicate devices.

A difference lies in the higher specialization of the MammoWorkstation for application to reading of mammograms. The capability to create structured report documents is not generic, it follows strictly the DICOM breast imaging report templates. Other differences lie in user interface and the degree of automation. The automatic hanging protocol or automatic scaling & alignment of images make mammography image reviewing more convenient to the user. This specialization does not pose any new issues of safety and effectiveness.

The intended use and technological characteristics of MammoWorkstation are substantially equivalent, in the opinion of Image Diagnost International GmbH to those of the predicate devices and to not pose any new issues of safety and effectiveness.

#### Conclusion:

Similar to the predicate devices, the MammoWorkstation does not contact the patient, nor does it control any life sustaining devices. Images and information being reviewed, processed, relayed, and or transmitted are interpreted by a physician or trained medical personnel, providing ample opportunity for competent human intervention.

Device failures, which might result in partial or failed transmissions, images, or data, may be recovered from storage or re-transmission after correcting the problem(s). Passwords are required for operation and to protect against unauthorized use.

Based on the information supplied in this 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUL 29 2008**

Image Diagnost International GmbH  
% Mr. Stefan Preiss  
Responsible Third Party Official  
TÜV SÜD America  
1775 Old Hwy 8 NW, Ste 104  
NEW BRIGHTON MN 55112-1891

Re: K081630

Trade/Device Name: Mammo Workstation  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: June 8, 2008  
Received: June 11, 2008

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

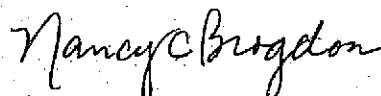
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number: &lt;unknown&gt;

Device Name: MammoWorkstation

## Indications For Use:

"MammoWorkstation is designed to assist radiologists in conducting primary diagnostic review for diagnostic and screening mammography through flexible and interactive manipulation of multi-modality softcopy images.

It provides image review, manipulation, analysis, post-processing and printing capabilities that support image management display needs in the medical environment.

MammoWorkstation is designed to give easy and economic access to and display of multi-modality softcopy images, structured reports, and CAD results through interfaces to various image storage devices using DICOM or similar interface standards. It supports creation of structured reports according to the DICOM breast imaging report templates.

MammoWorkstation supports teleradiology and teleconferencing providing access to multi-modality softcopy images and structured reports in multiple locations within and outside the hospital.

Lossy compressed mammographic images must not be used for primary diagnostic interpretation unless approved for use in digital mammography. ✓

Display monitors used for primary diagnostic interpretation of mammographic images must be approved for use in digital mammography. ✓

All images sent to or imported in the MammoWorkstation must conform to regulatory requirements. Image quality must conform with applicable quality guidelines. All modalities must be certified for soft-copy reading. ✓

(Source: Users Manual, MammoWorkstation Version 3.3.2, section 2.3.1)

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED) —

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

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